## EXHIBIT 615

## IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT MDL NO. 1968
LIABILITY LITIGATION

Kathy McCornack, an individual; MDL No.
Daniel E. McCornack, Jr., an 2:09-CV-0671
individual; and Ralph J. McCornack,

a minor by and through his guardian ad litem,

Plaintiffs

V.

Actavis Totowa, LLC, et al., Defendants.

Videotaped deposition of EDWARD J.

BARBIERI, Ph.D., taken at the Philadelphia Airport
Marriott, One Arrivals Road, Philadelphia,
Pennsylvania, on Monday, July 11, 2011, commencing
at 10:48 a.m., before Dianna R. Pugliese, a Registered
Merit Reporter, Certified Realtime Reporter, Certified
Shorthand Reporter-NJ, and Notary Public, pursuant to
notice.

PLAINTIFFS' EXHIBITS 012899

		Page 2			
1	APPEARANCES				
2	FOR THE PLAINTIFF:				
3	Don A. Ernst Esquire				
4	Ernst Law Group  de@ernstlawgroup.com  1020 Palm Street				
5	San Luis Obispo, California 93401 805-541-0300				
6					
7	FOR THE DEFENDANTS:				
8	Matthew P. Moriarty Esquire Tucker Ellis & West LLP				
9	matthew.moriarty@tuckerellis.com 1150 Huntington Building				
10	925 Euclid Avenue Cleveland, Ohio 44115-1475				
11	216-696-2137				
12					
13	Alicia J. Donahue, Esquire Shook, Hardy & Bacon, LLP Adonahue@shb.com				
14	One Montgomery Tower San Francisco, California 94105				
15	415-544-1900				
16					
17	ALSO PRESENT: Edward Amber, II, Video Operator Zanaras Court Reporting				
18					
19					
20	EXAMINATION INDEX				
<u> </u>	EDWARD J. BARBIERI, Ph.D.				
21	BY MR. MORIARTY 6				
2.0	BY MS. DONAHUE				
22	BY MR. ERNST 121 BY MR. MORIARTY 165				
23	BY MS. DONAHUE 174				
0.4	BY MR. ERNST 175				
24	BY MR. MORIARTY 177 BY MR. ERNST 178				
25					

			Page 3
1		EXHIBIT INDEX	
2	D 1 '	MARK:	ED
3	Barbieri		
4	Exhibit 1	Curriculum Vitae of Edward John Barbieri, Ph.D.	5
5	Exhibit 2	NMS Labs, Phone Log History Report	17
6	Exhibit 3	NMS Labs, NMS Legal Database Report	17
7	Exhibit 4	Plaintiffs' Summary of Non-Retained Expert Opinions Pursuant to Federal	20
8		Rules of Civil Procedure Rule 26(a)(2)(c)	
10	Exhibit 5	AHFS Drug Information 2011 excerpt	32
11	Exhibit 6	9/22/09 NMS Labs report	39
12		5/29/09 NMS Labs report	40
13	Exhibit 8	6/24/08 NMS Labs Supplemental Toxicology Report	48
14 15	Exhibit 9	July/August 2011 Journal of Analytical Toxicology Letter to the Editor by Fred Apple	78
16 17	Exhibit 1	Article from International Journal of Legal Medicine, Is vitreous humour useful for the interpretation of	83
18		3,4-methylenedioxymethamphetamine (MDMA) blood levels?	
19	Exhibit 1	l Clinical Toxicology article, Key Concepts in Postmortem Drug	85
20		Redistribution	
21	Exhibit 1	2 British Journal of Clinical Pharmacology article, Post-mortem	88
22		clinical pharmacology	
23	Exhibit 1	3 Clarke's Analysis of Drugs and Poisons, Third edition, Volume I excerpt	90
25		CVCEThc	

			Page 4
1	EXHIBIT	INDEX CONTINUED	
2		MARKED	
3	Exhibit	14 Clarke's Analysis of Drugs and 94 Poisons, Third edition, Volume II excerpt	
5	Exhibit	15 Journal of Clinical Pathology 96	
6		article, Estimating antemortem drug concentrations from postmortem blood	
7		samples: the influence of postmortem redistribution	
8	Exhibit	16 Journal of Analytical Toxicology 100 article, Mechanisms Underlying	
9		Postmortem Redistribution of Drugs: A Review	
10	Evhihi+	17 Excerpt from Postmortem Toxicology of 102	
11	EXNIDIT J	Abused Drugs by Steven B. Karch, M.D.	
12	Exhibit	18 Article by Gideon Koren, M.D. and 107 Ruth Parker, M.D., Interpretation of	
13		Excessive Serum Concentrations of Digoxin in Children	
14 15	Exhibit	19 Excerpt from Legal Medicine 1993 by 110 Cyril H. Wecht, M.D., J.D.	
16	Exhibit	20 5/2/2008 letter to Daniel McCornack 138	
17		from CVS Caremark	
18			
19			
20			
21			
22			
23			
24			
25			

Page 5 1 (Exhibit Barbieri-1 was marked for 2 identification.) VIDEO OPERATOR: This is the video 3 deposition of Dr. Edward Barbieri, taken by the 5 Defendant, in the matter of Kathy McCornack, et al., 6 versus Actavis Totowa, LLC, et al., in the U.S. 7 District Court for the Southern District of West 8 Virginia, Charleston Division, Case Number 2:09-CV-0671. 9 10 This deposition is being held at the 11 Marriott Hotel in Philadelphia, Pennsylvania, on July 11th, 2011. 12 13 My name is Edward Amber, and I'm the 14 videographer from the firm of Zanaras Court Reporting 15 with offices located in Philadelphia, Pennsylvania. 16 The reporter is Dianna Pugliese from the 17 firm of Rennillo Court Reporting with offices located 18 at 1301 East Ninth Street, Cleveland, Ohio. 19 We're going on the record at 10:48. 20 Counsel, please introduce yourselves. 21 MR. ERNST: Don Ernst representing Kathy 22 McCornack and the McCornack children as plaintiffs. 23 MS. DONAHUE: Alicia Donahue, Shook 24 Hardy & Bacon, representing the Mylan defendants. 25 MR. MORIARTY: Matthew Moriarty,

Page 6 1 representing the Actavis defendants. 2 VIDEO OPERATOR: Court reporter, please swear the witness in. 3 EDWARD J. BARBIERI, Ph.D., having been 5 duly sworn, was examined and testified as follows: 6 VIDEO OPERATOR: You may proceed. 7 EXAMINATION BY MR. MORIARTY: 8 9 Tell us your full name, please. 0. 10 Edward John Barbieri, spelled Α. 11 B-a-r-b-i-e-r-i. 12 And you go by Doctor by virtue of your 0. 13 Ph.D.? 14 Α. Yes. 15 Is this your most recent curriculum 0. 16 vitae? 17 Yes, it is. Α. 18 And it is marked as Barbieri Exhibit 1 Ο. 19 to this deposition, is it not? Yes, it is. 20 Α. 21 And the last revised date in the upper 0. 22 right-hand corner is February 1st, 2011. 23 Α. That's correct. 24 0. Correct. 25 Now, to put it plainly, are you a

Page 7 forensic toxicologist? 1 2 Α. Yes. 3 0. Do you have a degree in toxicology? Α. No, my degree is in pharmacology. Is toxicology a recognized specialty? 0. 6 Α. Yes. 7 Q. Have you made a career of toxicology? 8 Α. In the last 13 years I have. 9 All right. And correct me if I'm wrong, 0. 10 but I believe there are two paths that one can take to 11 get to the career of toxicology, one being the one you 12 have chosen, through a Ph.D. and practical experience; 13 correct? That's one. 14 Α. And another is that there are medical 15 0. doctors who have toxicology residencies or 16 17 fellowships; correct? 18 Yes. And they're usually considered as Α. 19 medical toxicologists. 20 0. Right. 21 Are you still a member of the Society of 22 Forensic Toxicologists? 23 Α. I am. 24 And SOFT, as it's known, does it have 0. 25 ethical guidelines for people like yourself testifying

Page 8 1 in settings such as this? 2 Α. Yes, it does. 3 0. Do you remember how many times you have testified in a civil case as an expert? 5 Not specifically, but multiple times. Α. 6 0. More than 50? I'd probably say less than 50. 7 Α. Have you testified in criminal cases? 0. 9 Α. Yes. 10 Do you have any idea how many of those 0. you have testified in? 11 12 Definitely more than 50. Α. 13 Q. More than a hundred? I think combined in court I've 14 Α. 15 testified, civil and criminal, over a hundred times. 16 By deposition, again, the total is 17 probably around 35 times. 18 All right. Because you probably don't Ο. 19 have depositions in criminal cases? 20 Α. Occasionally, but not often. 21 Do you have any idea about the 0. 22 percentage split of your forensic work between criminal and civil? 23 I haven't -- I haven't logged those, no. 24 Α. 25 In how many other digoxin cases have you Q.

Page 9 1 given testimony? 2 Α. One. 3 0. How many other pharmaceutical cases, pharmaceutical civil products liability cases? 5 I would say three others that I can remember. 6 7 Q. Have you given testimony about postmortem blood analysis and postmortem 8 redistribution? 9 10 Α. Yes. 11 Q. In the interest of -- let me take a step 12 back. 13 After those instances in which you gave testimony about postmortem blood analysis or 14 15 postmortem redistribution, did you ever have an 16 opportunity to review the transcript of your 17 testimony? 18 Α. In one specific case I did. 19 Q. All right. Do you know about any 20 others? In the others I have not. 21 Α. 22 Did you have that opportunity in the 0. 23 others? 24 Α. All of them I had opportunity to do 25 that.

Page 10 1 In order to be efficient today, I don't 2 wish to repeat too many things that you may have testified to in prior occasions. 3 Do you understand that? Α. Yes. 6 0. Are you confident that the testimony you 7 have given previously was recorded accurately? Yes, I am. 8 Α. 9 And did you make any efforts to change 0. 10 answers in prior testimony because on reflection you 11 thought you had made errors? 12 Α. No, I did not. 13 Q. So you would stand by answers that you have given under oath in previous cases? 14 15 Α. Yes. 16 Do you have any publications on 0. 17 postmortem redistribution? 18 Α. No. 19 Q. Do you have any on postmortem blood 20 analysis? 21 Α. No. 22 In other words, your own publications. 0. 23 Α. No. 24 In the last eight months, have you 0. 25 attended any continuing education conferences on

- 1 postmortem blood analysis or redistribution?
- 2 A. No, not in the past eight months.
- 3 Q. Do you know whether anyone from NMS Labs
- 4 was on the faculty of any continuing education
- 5 conferences regarding subjects of postmortem blood
- 6 analysis?
- 7 A. There was a session in Philadelphia
- 8 involving opioids in which postmortem came up as a
- 9 peripheral topic, which I attended.
- But that was not the main purpose of the
- 11 session. And there were two gentlemen from NMS that
- 12 were involved in that session.
- 13 Q. Do you --
- 14 A. But I don't know if they -- there was no
- 15 specific topic on postmortem redistribution at those
- 16 conferences.
- 17 O. Okay. So -- I mean, I know you're not
- 18 responsible for the constant monitoring of your fellow
- 19 toxicologists, but are you aware of any other
- 20 conferences at which your colleagues at NMS have been
- 21 on the faculty of continuing education regarding
- 22 postmortem blood analysis?
- 23 A. I'm not aware of it.
- 24 Q. Is Dr. Middleberg still one of your
- 25 colleagues --

Page 12 1 Α. Yes. 2 0. -- at NMS? 3 Α. Yes, he is. Q. Have you given any presentations at 5 professional meetings about postmortem blood analysis? 6 Α. I have discussed the topic, yes, at 7 coroner's conventions. 8 Q. All right. Have you ever talked about 9 postmortem redistribution? 10 Α. Yes, I have. 11 Q. And when was that? 12 Last year, there was a coroner's Α. 13 conference -- Pennsylvania coroner's conference in Pittsburgh that I mentioned PMR associated with 14 15 several drugs. 16 Do you have a slide deck or any hard 0. 17 materials from that conference or your presentation of 18 that conference? 19 Α. Yes, I do. 20 0. Where are those? 21 Α. In my computer and on a -- on a CD. 22 Okay. I would only ask that you keep 0. 23 those intact. 24 Α. Uh-huh, of course. 25 And maybe get access to those. Q.

Page 13 1 Α. Certainly. 2 0. Have you ever done any experiments or research, other than reading literature, into 3 4 postmortem blood analysis or postmortem 5 redistribution? 6 Α. I have not. 7 Q. Does NMS Labs perform serum digoxin assays on living people? 8 9 Α. Rarely. 10 In the non-litigation setting, do you 0. 11 have any personal experience with postmortem analysis 12 -- I'm sorry -- postmortem blood analysis of digoxin? 13 Α. In the non-litigation setting. Can you be more specific as to what you mean? 14 15 0. Sure. 16 Α. You mean other than testifying about the 17 topic? 18 Yeah. Other than a civil lawsuit or a 0. 19 criminal case --20 Α. Well --21 -- I assume digoxin wasn't involved in 0. 22 criminal cases, but --23 I'm going to object. MR. ERNST: 24 mean, I realize that I can only object, but he may be 25 testing for autopsies for a lot of different things

- 1 and it may or may not be considered litigation.
- THE WITNESS: And that's what I was
- 3 going to say. I mean, I've seen data coming through
- 4 the lab on postmortem blood levels of digoxin which I
- 5 have -- I have reviewed --
- 6 BY MR. MORIARTY:
- 7 Q. Okay.
- 8 A. -- for report. So I don't know if
- 9 they've ever gone to litigation.
- 10 Q. Okay.
- 11 A. I mean, this case is one that is now in
- 12 litigation.
- 13 Q. All right. So how often does that
- 14 happen?
- 15 A. Very rarely. We don't do very many
- 16 digoxins. It's not a common compound that comes up in
- our postmortem toxicology work. It has -- it's a
- 18 specialty test. It usually is requested.
- 19 Q. Very unusual for that to come up?
- 20 A. For us, yes.
- 21 Q. Okay. Do you recall ever a case in
- 22 which you actually consulted with a coroner about a
- 23 postmortem blood analysis of digoxin?
- 24 A. No.
- There was a case that goes back several

- 1 years in which there was a consultation that I had
- 2 with a researcher who was involved with a coroner in a
- 3 death case with digoxin. But never directly with a
- 4 coroner or medical examiner.
- 5 Q. Got it.
- Now, I've been asking you about
- 7 postmortem blood analysis regarding digoxin. What
- 8 about tissue, either vitreous, liver, or any other
- 9 tissue specimens; do you have any personal experience
- 10 with that regarding digoxin?
- 11 A. No. At NMS, I have not seen a single
- 12 case that's come through with a tissue or vitreous
- 13 level for digoxin personally.
- 14 Q. You have been involved, though, in a
- 15 litigation setting regarding a vitreous sample, have
- 16 you not?
- 17 A. Yes, I was.
- 18 Q. So are you aware that in the fall of
- 19 2009 I asked for a deposition of an NMS employee who
- 20 could talk about this stack of materials regarding
- 21 blood and tablet sampling in the McCornack case?
- 22 A. I'm aware of that now.
- 23 Q. Okay.
- 24 A. I wasn't aware at the time.
- Q. When did you first become aware of that?

- 1 A. Let me describe what happened and when I
- 2 became aware of it.
- 3 Mr. Ernst contacted me about this case,
- 4 I believe it was the end of May.
- 5 When I pulled up the work order number
- 6 for the particular case -- that's the biological part
- 7 of it -- I found out that we had produced a litigation
- 8 package on that case.
- 9 And that's when I became aware that
- 10 there was a deposition that had been done about this
- 11 case and the tablet involved with the case.
- 12 Q. All right. Are you done --
- 13 A. Before that, I knew nothing about that.
- 14 Q. Are you done with your answer?
- 15 A. Yes, sir.
- 16 Q. All right. Now, you did bring an NMS
- 17 file with you today; correct?
- 18 A. Yes, I did.
- 19 Q. And I don't know whether these are
- 20 duplicates for us today, but I assume they can come
- 21 out of a computer and be easily reproduced; correct?
- 22 A. They can be, yes.
- 23 Q. So can I mark these as exhibits with no
- 24 difficulty?
- 25 A. Yes, you may.

Page 17 1 (Exhibit Barbieri-2 was marked for 2 identification.) 3 BY MR. MORIARTY: So what I'm marking as Dr. Barbieri Q. 5 Exhibit 2, is this an NMS phone log history report? 6 Α. Yes, it is. This goes -- this goes from 7 April 2008 through September 16, 2009. All right. And the September 16, 2009 8 Q. 9 entry is actually the one about Dr. McMullin being 10 scheduled for a deposition with me or my office; 11 correct? 12 Α. Yes, that's correct. 13 MR. ERNST: May I look at that, please? (Attorney reviews document.) 14 15 Thank you. (Exhibit Barbieri-3 was marked for 16 identification.) 17 18 BY MR. MORIARTY: 19 Now, the next thing I'm going to mark is 20 Barbieri Exhibit 3. 21 And it is a two-page document; correct? 22 Α. Yes. 23 And essentially what this is is sort of 0. an adjunct to Exhibit 2 in that it documents phone 24 25 calls regarding the legal aspects of setting up

- 1 depositions and such; is that right?
- 2 A. Yes. Once a case goes into our legal
- 3 database system, the office staff generates this
- 4 format and then adds any notes to it for the case.
- 5 Q. Got it.
- 6 All right. So the first entry after
- 7 September of 2009 is May 27, 2011; is that right?
- 8 A. Yes.
- 9 Q. It says in this note that AMC -- who I
- 10 assume is Angela Cubbler?
- 11 A. Cubbler.
- 12 O. Cubbler?
- 13 A. Yes, that's correct.
- 14 Q. -- was asking why you were going to be
- deposed since Dr. McMullin was already deposed;
- 16 correct?
- 17 A. Yes.
- 18 Q. Do you see that?
- 19 A. Yes.
- 20 Q. Did you ever find out why you were going
- 21 to be deposed given the fact that he had already been
- 22 deposed?
- 23 A. Well, the short answer is Mr. Ernst
- 24 requested that I be deposed.
- 25 Q. Is there any reason?

Page 19 1 Α. I don't -- I don't know. 2 Ο. Okay. And then on Page 2, three more dates of communication about setting up this 3 4 deposition. 5 Yes, that's correct. Α. 6 MR. ERNST: Can I look at those, too? 7 (Attorney reviews document.) 8 Thank you. BY MR. MORIARTY: 9 10 Did you receive an e-mail from Terry 11 Kilpatrick of Mr. Ernst's office about whether you 12 were engaged, not engaged as an expert in this case? 13 Α. Yes. 14 0. Does it appear in this stack over here? 15 Α. I believe there is a document here, yes. 16 So what is your current understanding of 0. your status with respect to being an expert in the 17 18 McCornack versus Actavis case? 19 My understanding from that -- from the 20 discussion with Mr. Kilpatrick and the e-mail and the discussion with Mr. Ernst was that I'm listed as a 21 22 non-retained expert --23 0. Okay. 24 Α. -- to talk specifically about what we

did on this case in terms of the testing.

25

- 1 Q. Okay.
- 2 A. I have no -- I have not received any
- 3 information, other than what we have in the litigation
- 4 package, in terms of the case history, medical
- 5 records, or any other -- adjunct material about
- 6 Mr. McCormack or -- Mr. McCornack or the situation
- 7 involved.
- 8 Q. From looking at your documentation --
- 9 contact documentation in Exhibits 2 and 3, can you
- 10 tell whether you personally had any discussions with
- 11 Don Ernst or Terry Kilpatrick before May 15, 2011?
- 12 A. I know for a fact I did not.
- 13 Q. All right.
- 14 (Barbieri Exhibit 4 was marked for
- 15 identification.)
- 16 BY MR. MORIARTY:
- 17 O. Okay. Dr. Barbieri, I am handing you
- 18 what I have had marked as Barbieri Exhibit 4, since it
- 19 is my intention to off-load as much paper as possible
- 20 before I carry it home.
- 21 That is a document called Plaintiffs'
- 22 Summary of Non-Retained Expert Opinions Pursuant to
- 23 Federal Rule of Civil Procedure 26(a)(2)(c).
- Do you see that on the copy?
- 25 A. I do. I see that.

- 1 Q. And if you go back to Page 9, does your
- 2 name appear in Paragraph 4?
- 3 A. Yes, it does.
- 4 Q. And then it says Subject of Testimony,
- 5 Summary of Facts and Opinions, et cetera. And the
- 6 section regarding you spills over into about halfway
- 7 through Page 10; is that right?
- 8 A. Yes.
- 9 Q. Have you ever seen this before?
- 10 A. I've seen Pages 9 and 10 before.
- 11 Q. When did you first see Pages 9 and 10?
- 12 A. I saw them when you -- your office
- 13 responded to a contact from us inquiring why this
- 14 deposition was to go forward. And you provided a
- piece of this document, Pages 9 and 10, to me.
- 16 O. And there are letters in the stack here
- 17 that you brought. Those letters were in June of 2011;
- 18 correct?
- 19 A. Yes.
- 20 Q. So you did not have any discussions with
- 21 Mr. Ernst or Kilpatrick, or I assume anyone else from
- 22 his office, before this document was filed with the
- 23 Court May 16th, 2011; right?
- 24 A. That's correct. I had no contact with
- 25 them at that time, or prior to that time.

- 1 Q. Have you had any discussions with
- 2 Mr. Ernst or Kilpatrick about whether you are, in
- 3 fact, going to render the opinions that are listed on
- 4 Pages 9 and 10 if called to testify as a witness at a
- 5 trial in this case?
- 6 A. I did have discussions.
- 7 O. And tell me about that discussion.
- 8 A. I told them I would not render any
- 9 expert opinions concerning this case since I did not
- 10 have -- other than the testing that we had performed,
- 11 since I had no knowledge of all the things that I
- 12 talked about before in terms of medical records,
- 13 history, et cetera.
- 14 O. Okay.
- MR. MORIARTY: We have to just keep
- 16 these in an orderly way in here.
- MS. DONAHUE: Yes.
- 18 BY MR. MORIARTY:
- 19 Q. So other than the stack of NMS materials
- 20 that you brought, have you written any reports or
- 21 opinion letters in this case?
- 22 A. No, sir, I have not.
- 23 Q. Without rehash -- have you read
- 24 Dr. McMullin's deposition testimony?
- 25 A. No, I have not.

- 1 Q. Do you know whether this stack of
- 2 material, such of it as was available in the fall of
- 3 2009 when I came here and deposed him, is the same
- 4 material that was produced at his deposition?
- 5 A. I can only assume so since we kept that
- 6 in the file under the work -- under the expert number
- 7 for that deposition.
- 8 Q. Okay. So I do need to make sure that I
- 9 understand because there are some specific things I
- 10 need to know about.
- 11 There is an expert report in this case
- 12 by a pharmacist named Keith Gibson. Have you ever
- 13 seen his report?
- 14 A. No.
- 15 Q. And I assume you have not seen his
- 16 deposition testimony?
- 17 A. I have not.
- 18 And the name is not familiar. I've not
- 19 heard his name at all.
- 20 Q. Do you have a pharmacy license, by the
- 21 way?
- 22 A. Yes, I do.
- 23 Q. It's my understanding that you
- 24 personally do not render opinions on cause of death;
- 25 is that correct?

Page 24 1 Α. That's correct. 2 Ο. Do you render opinions on the diagnosis 3 of any diseases? Α. No. 0. Why not? 6 Α. Our job is to produce factual data for 7 the laboratory. If asked by a medical examiner my opinion in terms of potential causes of death or 8 9 influence of diseases on the data that we have, I'll 10 give opinions on that. 11 But I will not give scientific opinions 12 either on cause of death or disease -- disease states. 13 Q. Does Pennsylvania have a state law against the practice of medicine by non-licensed 14 physicians? 15 16 Α. I'm sure they do. 17 And in most or all cases, would 0. 18 rendering diagnoses about cause of death be the 19 unauthorized practice of medicine? 20 Α. It would be, yes. 21 0. Have you ever looked up any digoxin 22 dosing calculators on the Internet? 23 Α. Not that I can recall. 24 Do you know what the volume of 0. 25 distribution of digoxin is off the top of your head?

- 1 A. It's very -- it's very large.
- 2 Q. Do you --
- 3 A. Specific -- well, a specific number from
- 4 a reference that I have here, the volume of
- 5 distribution is between 5 and 7 liters per kilogram.
- 6 Q. Okay. So in a -- let's just say a
- 7 225-pound man, what would that volume of distribution
- 8 be?
- 9 A. Well, that's about 10 kilograms, so it
- 10 would be 10 times that number, between 50 and 70
- 11 kilograms -- or liters.
- 12 Q. The reference that you looked over at by
- 13 your left hand there, is that from Baselt's lab
- 14 manual?
- 15 A. Yes. This is the monograph on digoxin
- 16 by -- by Baselt. It's the 8th edition.
- 17 Q. Okay. Do you know whether digoxin is
- 18 universally distributed throughout the entire body?
- 19 A. Well, it's distributed throughout --
- 20 Q. I'm sorry, let me rephrase that because
- 21 I may have misspoken.
- Do you know whether digoxin is uniformly
- 23 distributed throughout the human body?
- A. Well, it is not.
- Q. Okay. Is it true that there's a high

- 1 concentration of digoxin in heart, brain, kidneys, but
- 2 the skeletal muscle forms the largest store of
- 3 digoxin?
- 4 A. In terms --
- 5 MR. ERNST: Objection as compound,
- 6 but...
- 7 THE WITNESS: In terms of total, because
- 8 there's much more skeletal muscle than there is the
- 9 other components.
- 10 On a concentration basis it's not. It's
- 11 certainly on a total amount, total mass, the answer
- 12 would be yes.
- 13 BY MR. MORIARTY:
- 14 O. So skeletal muscle could include
- 15 deltoids, triceps, biceps, pectorals, things of that
- 16 nature; correct?
- 17 A. Well, not could, it does.
- 18 Q. It does. Okay.
- 19 Does the Baselt reference that you have
- 20 there say what the bioavailability of digoxin in
- 21 tablet form is?
- 22 A. Yes, there's a notation of that.
- Q. What does it say?
- A. In tablet form, the bioavailability of
- 25 oral preparations ranges from 67 percent for tablets.

```
Page 27
 1
     It goes on.
 2
                               67.
                   MR. ERNST:
                   THE WITNESS: 67.
 3
                   So bioavailability for oral tablets is
 5
     0.67 according to this reference.
     BY MR. MORIARTY:
 6
 7
          Q.
                   67 to what?
          Α.
                   Of a hundred percent of the dose given.
 8
                   So of a -- of a hundred units of
 9
10
     medication taken orally --
11
          Q.
                   Right.
12
          Α.
                   -- 67 percent would get into the
13
     systemic circulation through the liver --
14
          0.
                   I got you.
                   -- and circulate.
15
          Α.
16
          Q.
                   I got you.
17
                   So they expressed it as a number, not a
18
     range.
19
          Α.
                   Yes.
20
          0.
                   So you tell me as a toxicologist, if
21
     that is true that the bioavailability is 67 percent,
22
     could the bioavailability of digoxin tablets increase
23
     by more than 50 percent?
24
          Α.
                   More than 50 percent of what?
25
                               Objection. Vague.
                   MR. ERNST:
```

- 1 don't...
- THE WITNESS: Yeah, I'm asking for a
- 3 clarification, too. I'm not sure what you mean.
- 4 BY MR. MORIARTY:
- 5 Q. Okay. You just said that according to
- 6 Baselt's the bioavailability is 67 percent.
- 7 A. Yes.
- 8 Q. Okay. Let's assume hypothetically that
- 9 there was something about the patient or the drug that
- 10 was going to increase the bioavailability of a
- 11 particular dose. Okay?
- 12 A. Uh-huh.
- 13 Q. Could it increase by more than 50
- 14 percent?
- 15 MR. ERNST: Objection. And I would
- 16 place it on the record what my objection is, but I'm
- 17 limited under Court Rule 22, so there's a number of
- 18 reasons, but that's what it is.
- 19 THE WITNESS: The bioavailability could
- 20 increase based on the factors you stated. Whether it
- 21 can go up to 50 percent, I don't know.
- 22 BY MR. MORIARTY:
- Q. No, I said by more than 50 --
- A. By more than 50 percent, I don't know.
- 25 It seems -- it seems a lot. But I don't know the

- 1 answer to that.
- 2 Q. Okay. Well, you could never have more
- 3 than a hundred percent bioavailability, could you?
- 4 A. You could not.
- 5 Q. So there were some other expert reports
- 6 in this case. There's a Dr. Hurd, who's a medical
- 7 toxicologist in Colorado.
- 8 Have you read his report?
- 9 A. No.
- 10 Q. Do you know who Dr. Hurd is?
- 11 A. No.
- 12 Q. And you haven't reviewed any company
- 13 documents from Actavis?
- 14 A. No, I have not.
- 15 O. No medical records of Dan McCornack?
- 16 A. None whatsoever.
- 17 Q. Have you read either of the two versions
- 18 of the autopsy report that were done by the coroner in
- 19 California?
- A. No, I have not.
- 21 Q. And I assume you haven't seen either
- 22 versions of the death certificate.
- A. No, I have not.
- Q. Do you see anywhere in the NMS records
- 25 that you or any other NMS toxicologist had any contact

- 1 directly with Dr. Mason, the coroner?
- 2 A. We had no direct contact that I can find
- 3 from any of the records that I saw with Dr. Mason.
- 4 Q. Is that --
- 5 A. Other -- let me -- let me preface it.
- 6 Other than the initial -- the original
- 7 test requisition form for the bio -- for the blood
- 8 work in which there was data written on that.
- 9 Now, whether Dr. Mason himself wrote it
- 10 or one of his colleagues wrote on that. That would be
- 11 the only contact I would have, but it was through that
- 12 one page.
- 13 Q. Okay. Now, if a toxicologist such as
- 14 you or Dr. McMullin had actually had a personal
- 15 discussion with Dr. Mason or a member of his staff, is
- 16 that the sort of information that would be documented
- 17 in your files?
- 18 A. Yes. That's one of the SOPs that when
- 19 we have phone conversations, we list a brief summary
- 20 of that conversation on our phone log notes. So that
- 21 would be in the files.
- 22 Q. So is there any evidence in the NMS file
- 23 that Dr. Mason contacted NMS to discuss the analysis
- 24 of either the tablet results or the blood results?
- 25 A. Not that I saw.

Page 31 1 Have you ever talked to Dr. Mason about 2 any case ever? 3 Α. I probably have. Q. Why do you say that? Α. Well, we have contact with a lot of our 6 clients, but I -- I don't have anything specific that 7 I can point to. I believe this is Santa Cruz County, but 8 0. 9 is Santa Cruz County considered a client of NMS? 10 Α. Yes, they are. 11 Q. This Baselt's book that you have at the 12 office and part of which you brought today, is that 13 something you refer to pretty much every day in your practice? 14 15 Α. Pretty much. 16 Do you refer to Clarke's Analysis of 0. 17 Drugs and Poisons? 18 Α. Yes, I do. 19 Q. Goodman & Gilman? 20 Α. Yes, I do. 21 And there is something called the Q. 22 American Hospital Formulary Service --23 Α. Uh-huh. 24 -- something like that? 0. 25 Α. I refer to that also.

Page 32 1 Ο. What is that? 2 Α. That's a publication put together by a 3 group of -- national group of pharmacists and physicians. 4 5 It's a various -- they have very 6 extensive monographs on many drugs, including the 7 pharmacology of the drug, the chemistry of the compound, stability information, a lot of information 8 9 from the PDR, blood levels if they're available, et 10 cetera. 11 (Exhibit Barbieri-5 was marked for 12 identification.) 13 BY MR. MORIARTY: 14 I've marked that as Barbieri Exhibit 5. 0. 15 Is this the book that you're talking 16 about? 17 This is -- yes, this is the most recent Α. 18 edition. I don't have this one. I have the one 19 that's a little earlier than this one. But this is -- this is the same text 20 21 that we're talking about. 22 While I've got this out, I want to ask 0. 23 you about it.

24 A. Okay.

Q. If you go back to Page -- oh, gosh.

25

Page 33 1 Α. On the bottom. 2 Ο. Yeah, it's cut off, but it looks like it's four digits, maybe 1737 -- no, 1727 is what it 3 is. 5 Α. Okay. I have it. 6 0. Is that the digoxin monograph from this 7 AHFS book that you're referring to? Yes. 8 Α. 9 And this is a book that you refer to in 0. 10 your own practice? 11 Α. Yes. 12 On the second-to-last page of Exhibit 5 0. 13 You're on Page 1729? 14 Α. 15 Q. Yes, sir. 16 Α. Okay. 17 In the beginning it says, Absorption: Q. 18 Following oral administration of digoxin in a tablet 19 or elixir, approximately 60 to 85 percent of the dose 20 is usually absorbed. 21 Do you see that? 22 Α. I do. 23 Is that different from bioavailability? 0. 24 Α. Well, it could be different. Absorption 25 is usually considered movement -- oral absorption --

- 1 movement from the gastrointestinal tract into the
- 2 portal circulation. Bioavailability includes movement
- 3 through the liver as well.
- 4 Q. Got it.
- 5 The next full paragraph in that section,
- 6 it says, There are interindividual variations in
- 7 plasma concentrations of digoxin with a -- with a
- 8 specific dose and in plasma concentrations of the drug
- 9 that produce therapeutic and toxic effects.
- 10 Did I read that correctly?
- 11 A. You did.
- 12 Q. Do you agree with it?
- 13 A. I do.
- 14 O. Tell me what it means.
- 15 A. It means that person to person taking
- 16 the same dose and even at the same body weight you
- 17 could have variations in the measured plasma
- 18 concentrations circulating.
- 19 Q. All right. And in the therapeutic and
- 20 toxic effects; correct?
- 21 A. Oh, yes. Because the -- the individual
- 22 sensitivity is not only based on plasma concentration
- 23 but it's based on the sensitivity of the individual to
- 24 that drug.
- 25 Q. Right.

- 1 So a -- to be more specific, a serum
- 2 digoxin concentration of 2.0 nanograms per milliliter
- 3 in one person may have a different effect and -- than
- 4 the same level on their twin; right?
- 5 A. Yes.
- 6 Q. A little further down, I think it's
- 7 maybe two sentences, three sentences down, it says, If
- 8 plasma concentrations of the drug are to be
- 9 determined, blood samples should be obtained at least
- 10 six to eight hours after the daily dose and preferably
- 11 just prior to the next scheduled daily dose.
- 12 Did I read it correctly?
- 13 A. You did.
- 14 Q. Is that your understanding that that's
- sort of the consensus in the scientific community?
- 16 A. Yes. The -- my understanding is at
- 17 minimum, the blood level -- the serum level should not
- 18 be taken for at least six hours. So six hours would
- 19 be the minimum. This says six to eight.
- 20 And prior to the next scheduled dose.
- 21 Basically they're looking at the -- the therapeutic
- 22 levels at trough concentrations.
- 23 Q. So if somebody said that when you sample
- 24 serum for digoxin that you were looking for peaks,
- 25 that's not consistent with your understanding of the

Page 36 1 methodology; is that right? 2 Α. No, it's not. 3 0. Let's skip one sentence. Well, let's not skip it. Therapeutic 5 plasma concentrations of digoxin in adults generally 6 are 0.5 to 2.0 nanograms per milliliter; correct? 7 Α. Yes. 8 0. Is that consistent with your 9 understanding? 10 Yes. I've seen references that go up Α. 11 to -- from 0.5 to 2.5. 12 Q. Okay. 13 Α. But other than that, we're in the same 14 range. 15 The next sentence says, In some patients with atrial fibrillation, slowing of ventricular rate 16 17 may require steady-state plasma concentrations of 2.0 18 to 4.0 nanograms per milliliter. 19 Do you see that? 20 Α. I do. 21 Q. Do you have any reason to agree or 22 disagree with it? 23 Α. No. 24 Do you agree with it? 0. 25 Α. Well, that's something that a physician

- 1 would really be involved with, and we would not get
- 2 involved normally with that. So that's not a number
- 3 that I keep in my head.
- 4 Q. Does that reflect back on the first
- 5 sentence of that paragraph where you're talking about
- 6 interindividual variations?
- 7 A. Yes, it would.
- 8 Q. So somebody who had a -- hypothetically,
- 9 somebody who had a serum level of -- digoxin level of
- 10 4.0, that would not necessarily mean that they have
- 11 digoxin toxicity; is that correct?
- MR. ERNST: Objection.
- 13 BY MR. MORIARTY:
- 14 O. You can answer.
- 15 A. Okay.
- MR. ERNST: You can answer.
- 17 And I would love to clarify it so the
- 18 record is clear. There are some rules that we are
- 19 still guided by. Normally when you make an objection,
- 20 lawyers can state the reasons why they wish to make
- 21 the objection.
- There has been some limitation placed by
- 23 the Court and all we can say is objection.
- THE WITNESS: Okay.
- MR. ERNST: So I am trying desperately

- 1 to abide by these rules, but it doesn't seem to make
- 2 sense to me. But I -- that's all I have.
- 3 THE WITNESS: Yeah, I'm sorry, could you
- 4 repeat the question for me.
- 5 BY MR. MORIARTY:
- 6 Q. I believe my question was, if you assume
- 7 hypothetically somebody had a serum digoxin level of
- 8 4.0 nanograms per milliliter, that doesn't necessarily
- 9 mean that that patient has digoxin toxicity; correct?
- MR. ERNST: Objection.
- 11 THE WITNESS: That's correct, it doesn't
- 12 necessarily mean that.
- 13 BY MR. MORIARTY:
- 14 Q. So if you look at the end of that
- 15 paragraph, there's an italicized sentence, isn't
- 16 there?
- 17 A. Yes.
- 18 Q. Serum concentrations of digoxin should
- 19 be interpreted in the overall clinical context. Thus,
- 20 an isolated serum concentration measurement should not
- 21 be used alone as the basis for adjusting dosage.
- Do you see that?
- 23 A. I do.
- 24 Q. Is that your understanding of the
- 25 consensus in the toxicological community?

- 1 A. Well, whether it's my understanding or
- 2 not in terms of the general consensus, as a
- 3 toxicologist, if a -- whether we're talking about a
- 4 toxic level in blood postmortem or an antemortem
- 5 level, a number is a number.
- 6 All of the information around that case
- 7 that helps to make someone understand that number is
- 8 just as important as the actual number that we get in
- 9 terms of the concentration.
- 10 Q. Okay.
- 11 A. So in isolation, a number is a starting
- 12 point. And one should not make a decision on any case
- 13 based upon just a number.
- 14 Q. And when you say "a decision on any
- 15 case, "you're talking about whether it's adjusting a
- dose, assigning a cause of death, any decision.
- 17 A. Any of those, yes.
- 18 Q. Did you read the tablet test results
- done by NMS to prepare for your testimony here today?
- 20 A. I flipped through that section of the
- 21 litigation package, so I'm aware of what the result is
- 22 on that published report.
- 23 (Exhibit Barbieri-6 was marked for
- 24 identification.)
- 25 BY MR. MORIARTY:

- 1 Q. Okay. I want to hand you what I've
- 2 marked as Dr. Barbieri Exhibit 6. Okay. And I'm
- 3 sorry about all the fax headers, but I had to have
- 4 this faxed to the hotel this morning.
- 5 This is a two-page document. Let me
- 6 just ask if that looks familiar to you.
- 7 A. I don't remember this one.
- 8 Q. All right.
- 9 A. I remember seeing one with a single
- 10 digoxin weight and thickness. I don't remember this
- 11 one. It may be in this package, but I just don't
- 12 remember. I may have missed it when I reviewed the
- 13 documentation.
- MR. MORIARTY: Well, let's do this
- 15 systematically.
- 16 (Exhibit Barbieri-7 was marked for
- 17 identification.)
- 18 BY MR. MORIARTY:
- 19 Q. I'm marking this as Barbieri Exhibit 7.
- 20 It was previously marked in Matt McMullin's depo as
- 21 Exhibit 2.
- Do you see that?
- 23 A. Yes.
- 24 O. Is this the one that looks familiar to
- 25 you --

Page 41 1 Yes, sir. Α. 2 -- as being in this litigation package? 0. Yes, it is. 3 Α. Q. Now, if a lawyer sent a second set of 5 tablets, would that get a separate work order number 6 at NMS? 7 Α. Not necessarily. If it came in and we knew it was coming in under the same work order, we 8 9 would like to put them together if we could. 10 If we're not aware of that, they may be logged in under a separate work order. 11 12 Do you know -- well, this Exhibit 6 0. 13 purports to be an NMS report to what was then the law firm of Ernst & Mattison; correct? 14 15 Α. Yes, it is. 16 And it refers to Dan McCornack right on 0. 17 here, doesn't it? 18 Yes, it does. Α. 19 Q. And it has a work order, 9154008. 20 Do you see that? 21 Α. Yes, I do. 22 Is that the same work order number that 0. is with the tablet analysis in the stack that you 23 24 brought with you? 25 Α. No, it's not.

Page 42 1 And then underneath it has a prior NMS 2 work order number, does it not? Yes. 3 Α. Q. 09107925. Α. 25. Is that the work order number for the 6 0. 7 tablet analysis that you brought? Α. Yes. 8 9 Just based on what I've shown you, does 0. 10 it appear that there was a second set of tablets sent 11 and analyzed by NMS? 12 MR. ERNST: Objection. 13 THE WITNESS: Yes, that's what it looks like. 14 BY MR. MORIARTY: 15 16 Were those tablets within the 0. 17 specifications? 18 Objection. MR. ERNST: 19 THE WITNESS: Well, within 20 specifications, I don't -- I can't answer that. I see the results of what is listed 21 22 here, and if I assume that they are 0.25 milligram 23 tablets, then it looks like at least most of them 24 would be within specifications. 25 There are two listed as 0.227. I don't

- 1 know if that is outside the manufacturer's
- 2 specifications for the tablet.
- 3 BY MR. MORIARTY:
- 4 Q. Okay.
- 5 A. But if they were 0.125, actually, then
- 6 they were not.
- 7 So without -- without knowing what the
- 8 tablets were, I really can't answer that question.
- 9 Q. Okay. If the -- if you assume these are
- 10 0.250 digoxin tablets and you assume that the
- 11 manufacturer's spec on the low side, which is FDA
- 12 approved, is 90 percent, then those two tablets are
- 13 still within the specs; correct?
- MR. ERNST: Objection.
- THE WITNESS: Yes.
- 16 BY MR. MORIARTY:
- 17 Q. All right.
- 18 A. They would all be within spec.
- 19 Q. Okay. And when you came here today, why
- 20 is it that NMS would not do a sweep, for lack of a
- 21 better term, for all of the McCornack work order
- 22 materials and that one be included in the stack?
- 23 A. Well, it's not that we wouldn't or we
- 24 couldn't. I was focused on -- at least I was asked to
- 25 talk about the biological testing that was done.

Page 44 1 And only because the original litigation package had one of those tablet cases involved was it 2 3 included here. Q. Got it. So, you know, I wasn't asked to review Α. 6 that other documentation. 7 Q. Okay. 8 Α. But we certainly would have if requested. 9 10 All right. And just for clarity of the 0. 11 record so people don't always have to refer to the 12 exhibits, there were five additional tablets in 13 Exhibit 6; correct? 14 Α. That's the way --15 MR. ERNST: Object --16 THE WITNESS: I'm sorry. 17 MR. ERNST: Objection. That makes an 18 assumption. 19 BY MR. MORIARTY: 20 0. Go ahead. 21 Α. That's the way it looks from the report. 22 Dr. Barbieri, I know you haven't seen 0. 23 this before, but when it describes the specimen, does

it say Five white pills in a cinnamon Altoids

container?

24

25

Rennillo Deposition & Discovery

- 1 A. Yes, it does. That's stated exactly the
- 2 way it's stated there.
- 3 Q. Does it say anything about whether that
- 4 was packed with tissue?
- 5 A. No, it doesn't.
- 6 Q. And just assuming that there was nothing
- 7 else in that Altoids container but five digoxin
- 8 tablets, would you agree with me that there would be
- 9 plenty of room for those tablets to rattle around in
- 10 the shipping process from California to Philadelphia,
- 11 Pennsylvania?
- MR. ERNST: Objection.
- 13 THE WITNESS: Well, I know that there
- 14 are big-sized Altoids packages and there's also these
- 15 minis. So if we're assuming that it's the regular
- 16 sized package, then, yes, I'd agree. If it's the
- 17 small one, maybe not.
- 18 BY MR. MORIARTY:
- 19 Q. Okay. Well, even a small one, five
- 20 digoxin tablets wouldn't take up a lot of space;
- 21 right?
- 22 A. Wouldn't take up a lot of space.
- 23 Q. Okay. Now, when NMS gets something in a
- 24 container like that, do they just take the tablets out
- or do they also assess the degree of residue that may

- 1 be left in the container from a digoxin tablet that
- 2 may have come off those in the shipping process?
- 3 A. That's a good question. I don't know
- 4 the specific answer to that.
- 5 If there was a single tablet and there
- 6 was a significant amount of residue in the container,
- 7 typically the chemist in charge of the case would
- 8 rinse all of that material out because that would have
- 9 all come from one tablet.
- In the case of five tablets, that may
- 11 have caused -- we could have a problem because we
- don't know which of those tablets, you know, caused
- 13 the residue.
- 14 So I really am having trouble answering
- 15 that because it may depend upon what the evidence
- 16 looks like.
- 17 O. Does NMS Labs have a website?
- 18 A. Yes, it does.
- 19 Q. Does NMS Labs' website have shipping
- 20 instructions for specimens?
- 21 A. I believe it does.
- 22 Q. Does the NMS instructions for shipping
- 23 specimens include cinnamon Altoid containers?
- A. I don't think that's on our website.
- 25 Q. And certainly if it did, you'd probably

- 1 counsel that it be packed with tissue to cushion the
- 2 blow; correct?
- 3 A. Absolutely.
- 4 MR. MORIARTY: Okay. I'm sorry, Miss, I
- 5 took that from you.
- 6 BY MR. MORIARTY:
- 7 Q. So getting back to something you were
- 8 talking about quite some time ago on whether you were
- 9 going to offer opinions, I assume that -- well, I'll
- 10 just ask you: Are you going to testify that the
- 11 tablets Mr. McCornack ingested prior to his death
- 12 contained anything other than the labeled amount of
- 13 digoxin?
- 14 A. I have no basis for testifying to that,
- 15 so, no, I would not.
- 16 Q. Okay. Are you going to render any
- 17 opinions about whether Mr. McCornack had digoxin
- 18 toxicity or whether digoxin played any role in his
- 19 death?
- 20 MR. ERNST: I'm going to object and I --
- 21 THE WITNESS: I'm not going to testify
- 22 to that.
- MR. MORIARTY: I'm going to mark this as
- 24 Dr. Barbieri Exhibit 8. It was formerly marked as
- 25 McMullin Exhibit 3.

- 1 (Exhibit Barbieri-8 was marked for
- 2 identification.)
- 3 BY MR. MORIARTY:
- 4 Q. Okay. Is that the blood analysis for
- 5 the McCornack specimen?
- A. Yes. This is the second report,
- 7 toxicology report, that I authored on this case.
- 8 Q. All right. And for lack of a better
- 9 term, you were what is known as the -- I'm sorry --
- 10 supervising toxicologist; is that right?
- 11 A. At which time? When I did this case?
- 12 O. Yes.
- 13 A. Well, I was the toxicologist who did the
- 14 report for this case.
- Okay. So what is your title with
- 16 respect to this case?
- 17 A. I'm the person who reviewed the data and
- 18 signed the report.
- 19 Q. Who actually ran the blood through
- 20 whatever tests are done?
- 21 A. We have a whole lab staff, and there are
- 22 people in the lab in different departments that would
- 23 have done different pieces of this analysis. And some
- 24 of the screen data as well.
- 25 Q. So your role is then what?

- 1 A. My role would be to take the data, some
- of it original data, some of it through the computer,
- 3 review that data, make sure it makes sense in terms of
- 4 what I see in the case, generate a report listing the
- 5 specimens, what was requested, the factual results
- 6 that we obtained, and to publish that in a signed
- 7 report with certain reference comments that the report
- 8 could be modified by me.
- 9 And then at the end, to list everything
- 10 that we did in terms of testing.
- 11 Q. Got it.
- MR. ERNST: And this is Number 8?
- MR. MORIARTY: 8.
- 14 THE WITNESS: Yes.
- 15 BY MR. MORIARTY:
- 16 Q. And I assume you have not read
- 17 Dr. McMullin's testimony regarding this document?
- 18 A. I have not.
- 19 Q. Did you talk to him about it?
- 20 A. After the first phone call that I
- 21 received from Mr. Ernst and he mentioned Matt
- 22 McMullin's name, that he was deposed on the case, and
- 23 then, of course, as we pulled up the records I found
- 24 that out, I went to Matt McMullin and I said to him,
- 25 Do you remember being deposed on the McCornack case?

- 1 And he says he remembers being deposed
- 2 on two cases that involved tablet testing and there
- 3 was one of them with biologicals.
- And I said, Can you tell me anything
- 5 about -- because I don't know why I'm being deposed
- 6 again.
- 7 And he said, no. There was a lot of
- 8 discussion, there were a lot of people in the room.
- 9 But he said they -- his memory was that the focus was
- 10 on the tablets.
- 11 So that was the extent of our
- 12 conversation. And I just assumed that I was going to
- 13 talk about the biologicals.
- Q. Okey-doke.
- Now, if you look at the -- I'm sorry,
- 16 let me take a step back.
- 17 Have you ever seen lab tests that are
- 18 done for clinical purposes?
- 19 A. Yes.
- 20 Q. And typically in a lab test done for
- 21 clinical purposes, there is the result; correct?
- 22 A. Yes.
- 23 Q. And then near it somewhere, above it or
- 24 to the side, is typically the lab's reference range
- 25 for that -- whatever that test may be; correct?

Page 51 1 Α. Yes. 2 So if they're doing a red blood cell Ο. count, it will say RBC, then it will have that 3 patient's red blood cell count; correct? 4 5 Α. Yes. 6 0. And then typically in parentheses off to 7 the side it will say what the normal red blood cell count in that lab should be; right? 8 9 Α. Yes. 10 All right. And that information in 0. 11 parentheses, do you call that the reference range? 12 Α. Generally. 13 Q. Now, on Exhibit 8, whether it's for alcohol, diltiazem, digoxin, there is no reference 14 range next to those figures, is there? 15 16 Α. Right. 17 On a forensic report, we don't put that 18 on the -- on the front under the Findings. Many times 19 if we know what it is, we would put it in the Comments 20 section on the back. 21 Okay. So --0. 22 Α. Can I add to that? 23 0. Sure. If this was a clinical case with a 24 Α.

clinical format report -- we have those for our

25

- 1 clinical clients -- what you described would be on the
- 2 report.
- 3 Q. And the reason it is not on the report
- 4 is because this is not a clinical case, this is a
- 5 forensic case; right?
- 6 A. Yes.
- 7 Q. And there is no reference range for dead
- 8 people; right?
- 9 MR. ERNST: Objection.
- 10 THE WITNESS: That's true.
- 11 BY MR. MORIARTY:
- 12 Q. Okay. So, for example, for diltiazem,
- there is no known figure for what the diltiazem level
- 14 should be, if any, in somebody who died.
- 15 A. Well, in terms of therapeutic. I mean,
- 16 we have reference ranges that we add in terms of
- 17 people taking a certain dose and finding postmortem
- 18 blood levels of X to Y.
- 19 Q. Right.
- 20 A. But they're not therapeutic ranges, per
- 21 se, like antemortem would be.
- 22 Q. Got it.
- So if you go to Page 2, Paragraph 2,
- 24 this is talking about diltiazem; right?
- 25 A. Yes.

- 1 Q. And at the end of the first paragraph --
- 2 at the beginning of the second paragraph it says,
- 3 Therapeutic blood levels of diltiazem appear to be in
- 4 the range of 50 to 200 nanograms per milliliter;
- 5 correct?
- 6 A. That's correct.
- 7 Q. And what that is referring to is that in
- 8 the living, from your review of the literature, this
- 9 is what you would expect to see in a patient who was
- 10 being monitored for diltiazem; yes?
- 11 A. Yes.
- MR. MORIARTY: We have two minutes left
- 13 on the first tape. How time flies. So we might as
- 14 well take a five-minute break.
- THE WITNESS: Okay.
- 16 VIDEO OPERATOR: We're going off the
- 17 record at 11:46.
- 18 (A recess was taken from 11:46 to
- 19 11:51 a.m.)
- 20 VIDEO OPERATOR: We're back on the
- 21 record at 11:51.
- You may proceed.
- 23 BY MR. MORIARTY:
- Q. All right. Dr. Barbieri, I want to ask
- you some questions about the blood sample.

- 1 And just to cut straight through it, I
- 2 want you to assume that Dr. Mason, the coroner, has
- 3 testified that he drew the specimen from an axillary
- 4 vein. Okay?
- 5 A. Okay.
- 6 Q. Do you know where the axillary vein is?
- 7 A. It's up here (indicating) in your arm.
- 8 Q. Are you pointing to the arm, the
- 9 shoulder --
- 10 A. Well, it's right in this area
- 11 (indicating). It's near the subclavian. And the
- 12 axilla -- this is the axilla (indicating), so it would
- 13 be right in the junction between the arm and the
- 14 shoulder area.
- 15 Q. Okay. From your understanding of the
- 16 literature, is the axillary vein even referred to
- often as a draw site for postmortem blood analysis?
- 18 A. Well, it's been referred to. It's not a
- 19 common one.
- 20 Q. And would you agree with me that it is
- 21 not a true peripheral specimen?
- MR. ERNST: Objection.
- 23 THE WITNESS: In terms of certain
- 24 pathologists, they consider it a peripheral site.
- In terms of a toxicologist, myself, I do

- 1 not consider it a peripheral site.
- 2 BY MR. MORIARTY:
- 3 Q. Why?
- 4 A. It's too close to the chest cavity.
- 5 Q. What was the total sample size between
- 6 the two vials of blood?
- 7 A. The way we have them listed on the
- 8 report, per our quick measurement, the total sample
- 9 size was 24 mL's of blood.
- 10 Q. Do you have any knowledge or opinion as
- 11 to the blood volume of an axillary vein?
- 12 A. No, I wouldn't know.
- 13 Q. Do you know anything about whether a
- 14 specimen should be -- I'm sorry -- a -- let me start
- 15 over.
- Do you know anything from your own
- 17 toxicological experience about whether it is advisable
- 18 to ligate a vessel before drawing a postmortem blood
- 19 specimen?
- 20 A. It's the preferred way of taking a
- 21 specimen.
- 22 Q. Why?
- 23 A. Because it prevents a back flow from
- 24 upstream so that you don't get contamination from
- 25 sites away from the draw site.

- 1 Q. Okay. So what would the danger of -- be
- 2 of drawing 24 milliliters of blood from a non-ligated
- 3 axillary vein?
- 4 MR. ERNST: Objection.
- 5 THE WITNESS: Well, the only danger is
- 6 it's not a pure axillary vein sample.
- 7 BY MR. MORIARTY:
- 8 Q. Okay.
- 9 A. You may have -- you may have blood
- 10 that's being pulled from closer to the chest as it's
- 11 being drawn. I'm assuming that the -- the draw is
- 12 going up toward the chest and not downward.
- 13 Q. Okay. So the danger is that the draw
- 14 would get subclavian blood?
- 15 A. Subclavian blood comes off -- yes, that
- 16 would be the site of contamination, again, if it's
- 17 being pulled in this direction.
- 18 Q. And obviously you don't know anything
- 19 about the volume of an axillary. You probably don't
- 20 know about the volume of a subclavian vein either, do
- 21 you?
- 22 A. It's -- it's bigger.
- 23 Q. Okay. But, in general, the overall
- 24 danger -- and when I say "danger," I mean to the
- 25 integrity of the specimen or the quality of the

- 1 specimen -- is that you're drawing blood from closer
- 2 to the heart than you want to.
- 3 A. Yes.
- 4 Q. Does NMS's website have a collection
- 5 procedure on it?
- 6 A. There are submission procedures. I
- 7 don't believe that we give collection procedures in
- 8 terms of how to draw samples.
- 9 Q. Is -- whatever procedures are out there,
- 10 are they designed to lower the risk of analytical
- 11 error?
- 12 A. Yes.
- 13 Q. Does NMS say on its website that it
- 14 prefers femoral samples?
- 15 A. Yes.
- 16 Q. Does NMS on its website say that it
- 17 prefers more than one location of sample?
- 18 A. Yes.
- 19 Q. Does the NMS website say that it prefers
- 20 samples from the heart and the femoral vein?
- 21 A. Yes.
- 22 Q. In this case, did Dr. Mason do either?
- MR. ERNST: Objection.
- 24 BY MR. MORIARTY:
- 25 Q. To your knowledge?

- 1 A. Well, to my knowledge, I don't know
- 2 that. He did not submit the heart and peripheral
- 3 blood as two different sample sites.
- 4 Q. Okay.
- 5 A. The two peripheral samples could have
- 6 come from two sites. I don't know that.
- 7 Q. All right. But -- okay.
- 8 Does the NMS website also list various
- 9 other types of specimens such as vitreous and liver?
- 10 A. It does.
- 11 Q. Are those options available so that you
- 12 can cross-check your results and do the best you can
- 13 to give accurate results?
- 14 A. Yes. If a problem comes up and we have
- 15 an additional sample that saves the client in terms of
- 16 shipping costs and delays in testing an alternate
- 17 specimen, such as the liver or vitreous.
- 18 Q. Well, what is the risk, if you will,
- 19 from a forensic toxicological standpoint of just
- 20 having one blood specimen as the only matrix that
- 21 you're analyzing?
- 22 A. Well, one risk would be that the sample
- 23 could have been contaminated at the site, at the
- 24 autopsy site.
- 25 Another risk is that the draw site could

- 1 have -- does not represent really what's happening
- 2 with the individual.
- 3 Let me give you a case in point. You
- 4 have an individual who has an i.v. morphine drip into
- 5 the arm, the left arm, per se, and that's all
- 6 disconnected after the person dies.
- 7 And at autopsy, they take a sample from
- 8 the left arm. Well, the concentration of morphine in
- 9 that left arm is going to be significantly greater
- 10 than it would be in the femoral blood, for example.
- 11 So that -- if we had two different
- 12 samples, we would say, These results make no sense
- 13 based on the history you're giving us. Let's test
- 14 something else. Let's test the liver or femoral blood
- 15 sample or the vitreous.
- 16 Q. Okay.
- 17 A. Okay?
- 18 Q. Do you know whether NMS measured the
- 19 digoxin concentration in -- I'm sorry, withdraw that
- 20 question.
- This is a whole blood sample, not a
- 22 serum sample; correct?
- 23 A. This is -- yes. It's postmortem blood
- 24 we consider as whole blood, though it's not really
- 25 whole blood as we think about it in a living person.

Page 60 1 Is there an analytical difference 2 between whole blood and serum? Very much so. 3 Α. Q. What's the difference? Serum does not contain deformed Α. 6 elements. It's just the liquid portion of a clotted 7 sample. 8 0. My question was poor. 9 If you were somehow able to draw a 10 sample at the same time and analyze it from a whole 11 blood standpoint and a serum standpoint, would the 12 numbers come out different? 13 Α. They may. All right. And how would they be 14 0. different? 15 16 Α. Well, certain drugs distribute 17 differently into the formed elements of whole blood 18 than they do into the liquid portion. Ethyl alcohol 19 would be a perfect example. 20 0. What about digoxin? 21 Α. Digoxin, the ratio that's been in the 22 literature is whole blood versus serum -- plasma that 23 they used is 1 to 1.1, so it's close. A little bit

higher in blood than in plasma or serum.

Q.

24

25

Okay. And do you have to take that into

- 1 account in interpreting postmortem whole blood
- 2 analysis?
- 3 A. Yes. It's very important to take that
- 4 into account. Especially if there's a big difference
- 5 between the two.
- 6 O. You've heard the term "error rates"?
- 7 A. Yes.
- 8 Q. What's the error rate of the whole blood
- 9 postmortem digoxin analysis in this type of case?
- 10 A. Well, what we would do in this case if
- 11 we had to answer that question is replicate samples
- would have to agree within plus or minus 20 percent of
- 13 each other. That would be the error rate for the
- 14 analysis -- for the total analysis.
- That doesn't mean that any one sample is
- off by 20 percent. It just means corresponding
- 17 between two replicate analyses.
- 18 Q. If you had two.
- 19 A. If we had two.
- 20 Q. In your experience as a forensic
- 21 toxicologist, how reliable is a liver specimen for
- 22 quantifying digoxin postmortem?
- 23 A. Not that reliable.
- 24 Q. Did you have a liver sample available to
- 25 you in this case?

Page 62 1 There was a liver submitted, yes. Α. 2 0. Was it ever run? No, it wasn't. 3 Α. Q. Why? 5 It wasn't asked to be run. Α. 6 0. Who does the asking? Is it Mr. Ernst's 7 office or Dr. Mason's office? Well, in this case, the original sample 8 Α. 9 came in from the Santa Cruz County coroner, so they're 10 They would have to do the asking. our client. 11 We're -- we're different than a state 12 lab or a government lab who may look at results and 13 want to do every sample tested. Everything we do we 14 charge for and that would be unethical for us to do 15 work like that. 16 0. Sure. 17 Tell us the sort of things that happen to tissue and blood, even in a properly preserved 18 19 body, when you get out to 70 to 78 hours postmortem. 20 MR. ERNST: Objection. 21 But you can go ahead and answer the 22 question. 23 THE WITNESS: Well, in terms of blood, 24 the cells are breaking down. The red cells are 25 hemolyzing. The white cells are hemolyzing.

- 1 That's why the sample, we call it whole
- 2 blood, but it really has no relationship to real whole
- 3 blood anymore.
- 4 You could have tissue products that are
- 5 going into the blood and it becomes contaminated with
- 6 tissue fluids as the walls of the arteries or the
- 7 veins break down as well.
- 8 The same thing happens in the liver or
- 9 any other tissue. Tissue necrosis occurs. Postmortem
- 10 artifacts occur.
- And so, you know, you do the best you
- 12 can with what you have, but it's not representative,
- 13 necessarily, of what was there immediately after the
- 14 person died.
- 15 BY MR. MORIARTY:
- 16 Q. Are there things called proteolysis and
- 17 tissue autolysis that occur?
- 18 A. Yes, that does occur.
- 19 Q. I forgot to ask you this up front.
- 20 Have you and I ever talked about this
- 21 case before we went on the record today?
- 22 A. No, we have not.
- 23 Q. How much time have you spent talking to
- 24 Mr. Ernst before we went on the record today?
- 25 A. The first phone call was I guess about

- 1 40 -- 40 to 45 minutes.
- 2 There was a subsequent phone call that
- 3 occurred with Mr. Kilpatrick that was maybe five or
- 4 ten minutes.
- 5 And then there was a follow-up phone
- 6 call which did not have anything to do specifically
- 7 with the case, it was more my misunderstanding of what
- 8 was written in one of those documents that I objected
- 9 to, and he -- Mr. Ernst contacted me and tried to
- 10 explain the purpose of what was written there.
- 11 Q. Okay.
- 12 A. So that was another maybe five to ten
- 13 minutes.
- 14 I think that's the total conversations
- 15 that we've had.
- 16 Q. All right. When you say a
- 17 misunderstanding about something written in the
- 18 document, are you talking about Exhibit 4?
- 19 A. Yes. This was Pages 9 and 10 that we
- 20 talked about before.
- 21 Q. Okay. Now, Drs. Middleberg, Logan, you,
- 22 McMullin, are all available, theoretically, to give
- 23 testimony about postmortem blood analysis for
- 24 specimens run at NMS; correct?
- 25 A. Yes.

- 1 Q. Do you gentlemen have meetings to
- 2 discuss this scientific principle in order to assure
- 3 that you are on the same page?
- A. Not necessarily. I mean, we -- we have
- 5 toxicology meetings and we have meetings to discuss
- 6 casework. We don't specifically talk about topics
- 7 like this.
- 8 We may bring up a case where a paper is
- 9 written about postmortem redistribution, and we want
- 10 -- everybody reads it and we talk about it. Kind of a
- 11 journal club type of thing. So those topics have come
- 12 up.
- 13 Q. Okay.
- A. But it's not a formal meeting to do
- 15 that.
- 16 Q. Well, how would you know, for example,
- 17 whether you are saying something under oath that is
- 18 consistent with what your colleagues in the same
- 19 practice are saying under oath in a different case?
- 20 A. Well, we -- we talk about cases that
- 21 have come up and how the testimony went and what the
- 22 questions are and what the issues are. Especially if
- 23 there are unusual circumstances.
- Q. Okay. And then do you keep an archive
- 25 or try to keep an archive of the pieces of medical

- 1 literature that lawyers ask you about?
- 2 A. Well, we all have our own reference
- 3 files, you know, paper copies of references.
- We also have a sentry on our -- we have
- 5 a computer drive that has nothing but reference
- 6 articles, they're all stored electronically.
- 7 So if something comes up like an out --
- 8 broken out by drug, by events like postmortem
- 9 redistribution or distribution of bioavailability.
- 10 So we all have access to those files.
- 11 We all share our own files as well so that we
- 12 distribute information among the group.
- 13 Q. Does NMS keep a record of all the
- 14 postmortem digoxin specimens that it has run?
- 15 A. Our IT department can get that
- 16 information. We can -- we can start a list from --
- 17 you know, giving a certain date range of all the
- 18 digoxin values and then we can list it by forensic
- 19 cases versus clinical cases, for example.
- Now, in those forensics cases, there may
- 21 be cases that are not postmortem. We wouldn't know
- 22 that. We'd have to search back into the
- 23 documentation.
- So it's limited, but we can get some of
- 25 that information.

- 1 Q. So, sitting here today, you wouldn't
- 2 know where this digoxin result of 3.6 stands in
- 3 relation to other postmortem levels that your lab has
- 4 done.
- 5 MR. ERNST: Object --
- THE WITNESS: No, I wouldn't know that
- 7 as I sit here today.
- 8 MR. ERNST: Objection.
- 9 BY MR. MORIARTY:
- 10 Q. Does digoxin undergo postmortem
- 11 redistribution at multiple locations in the body?
- 12 A. Yes.
- 13 Q. Does it happen at peripheral sites?
- 14 A. It would happen at peripheral sites
- 15 through diffusion from skeletal muscle into the
- 16 bloodstream, yes.
- 17 Q. So even in a true peripheral sample,
- 18 like a femoral sample, you would expect there to be
- 19 some postmortem redistribution of digoxin, depending
- 20 on the timing of the postmortem draw; correct?
- 21 A. I would expect that there would be
- 22 some. It would be certainly much less than it would
- 23 be from a blood sample taken from the chest.
- 24 Q. All right. Do you know how long after
- death the postmortem draw was in this case?